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APR 15 2005

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker® Patient Specific Polymer Implant

General Information

Proprietary Name:	Stryker® Patient Specific Polymer Implant
Common Name:	PMMA
Proposed Regulatory Class:	Class II
Device Classification:	KKY (882.3500)
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 269-323-4226
Submitter's Registration #:	1811755
Manufacturer's Registration #:	1226001
Contact Person:	Wade T. Rutkoskie Associate Manager RA QA Phone: 269-323-4226 Fax: 269-323-4215
Summary Preparation Date:	November 20, 2004

Intended Use

The Stryker® Patient Specific Polymer Implant is designed individually for each patient to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone.

Substantial Equivalency Information

The Stryker® Patient Specific Polymer Implant is substantially equivalent to the Hard Tissue Replacement – Patient Match Implant K924935, Hard Tissue Replacement – Malleable Facial Implant, Hard Tissue Replacement–MX K904111, Surgical Simplex P Radiopaque Bone Cement (Howmedica Osteonics N-17-004).

The Stryker® Patient Specific Polymer Implant is manufactured by Doctor's Research Group. The Stryker® Patient Specific Polymer Implant is made from PMMA, specifically Surgical Simplex P Radiopaque Bone Cement.

Surgical Simplex P Radiopaque Bone Cement is a biocompatible nonresorbable material that will maintain its shape after implantation and provide protection to the skull. Surgical Simplex P Radiopaque Bone Cement is a porous composite material comprised of polymethylmethacrylate (PMMA). PMMA has been used for decades in various applications from clinical orthopaedics to oral surgery since the 1930's. Clinical use of Surgical Simplex P Radiopaque Bone Cement has been used in thousands of cases proving to be safe and effective.

The safety and effictiveness of Surgical Simplex P Radiopaque Bone Cement has been established over several decades. The implant will be designed and molded for a specific patient to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone. A Patient Specific Polymer Implant provides for replacement of an amorphous shaped implant not contained within standard product offerings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. Nathan M, Miersma
Regulatory Affairs Representative
Stryker
4280 Commercial Avenue, Suite A
Portage Commerce Park
Portage, Michigan 49002

Re: K043250
Trade/Device Name: Stryker Leibinger Patient Specific Polymer
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: KKY
Dated: March 13, 2005
Received: March 15, 2005

Dear Mr. Miersma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043250

Device Name: Stryker Leibinger Patient Specific Polymer

Indications For Use:

The Stryker® Patient Specific Polymer Implant is designed individually for each patient to correct trauma and/or defects in madibular, maxillofacial, or craniofacial bone.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K043250